1257328

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

December 06, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: *60/512,657*
FILING DATE: *October 20, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/34864*

Certified by

Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
and Acting Director of the U.S.
Patent and Trademark Office

PTO/SB/16 (08-03)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EL991581482US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Ronald D.	Berger	Baltimore, MD

Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Catheter and Method for Ablation of Atrial Tissue

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ Customer Number:

OR

☑ Firm or Individual Name	Johns Hopkins University				
Address	100 N. Charles Street				
Address	5th Floor				
City	Baltimore	State	MD	Zip	21201
Country	USA	Telephone	410-516-8300	Fax	410-516-5113

ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 7 ☐ CD(s), Number _____

☑ Drawing(s) *Number of Sheets* 3 ☐ Other (specify) _____

☐ Application Date Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees.

☐ The Director is herby authorized to charge filing fees or credit any overpayment to Deposit Account Number: _____

☑ Payment by credit card. Form PTO-2038 is attached.

FILING FEE Amount ($): $80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____ Date 10/20/03

TYPED or PRINTED NAME Heather Barabyar, Ph.D. REGISTRATION NO. 45,282 *(if appropriate)*

TELEPHONE 410-516-8300 Docket Number: 4301

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

CERTIFICATE OF EXPRESS MAILING

EXPRESS MAILING LABEL NO.

EL991581982US

I hereby certify that this correspondence (along with any papers referred to as being attached or enclosed) is being deposited with the United States Postal Service as Express Mail, Post Office to Addressee with sufficient postage in a **Flat Rate** envelope addressed to MS Provisional Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below:

10/20/03
DATE of Signature
And of Mail Deposit

Cheryl Alexwood
Signature

New Tech

Johns Hopkins University
Licensing and Technology Development

Report of Invention Disclosure Form

This form is to be completed and submitted to the JHU office of Licensing and Technology Development (LTD) by anyone who believes they have developed a new invention. The purpose of this form is to enable LTD to evaluate whether legal protection to the invention will be sought and/or commercialization pursued. In order for this Report of Invention to be processed by LTD, it must be signed and dated by all inventors, and by the JHU Department Director(s) for all departments involved with the development of this invention. LTD can not process this report until it is complete with all necessary signatures found in Sections A, B and/or C. Visit the LTD web site at http://www.jhu.edu/technology/roi.html for HTML and Word downloadable formats of this form.

INVENTION INFORMATION

Title of Invention:
Catheter and Method for Ablation of Atrial Tissue

School(s) and Department(s) in which invention was developed: School of Medicine, Dept. of Medicine

Additional inventors: ☐ Yes ☒ No If yes, please complete Additional Inventors section for each inventor.

Lead Inventor Information: ["The Lead Inventor is the primary contact person for LTD on all matters associated with this Report of Invention, including processing, patent prosecution and licensing. For reasons of administrative efficiency, it is the responsibility of the Lead Inventor to keep all other JHU inventors named on this Report of Invention informed of the status of such matters."]

Name of Lead Inventor: Berger (Last) Ronald (First) D. (Middle) MD, PhD (Degree)

Title or Position: Assoc. Prof. Of Medicine School: Medicine Department: Medicine

Business phone: 4-2751 Business fax: 4-1345 E-mail: rberger@jhmi.edu

Business address: Carnegie 592, 600 N. Wolfe St., Baltimore, MD 21287

Interdepartmental address: Carnegie 592

Home address: 3101 Northbrook Rd., Baltimore, MD 21208

Citizenship: USA

Are you a Howard Hughes Medical Institute employee or investigator? ☐ Yes ☒ No

Are you a Kennedy Krieger Institute employee or investigator? ☐ Yes ☒ No

LTD Internal Use Only: REF 4301 TLA NAL Field of Use 2E

INVENTION DESCRIPTION

Describe the invention completely, using the outline given below. Please provide an **Electronic Copy** of the invention disclosure document, references, and abstracts, in Windows format, on CD-Rom or Floppy Disk.

1. **Abstract of the Invention** [In order to assist Licensing and Technology Development with the assessment of this technology, please provide a summary of the invention that should be written to be understood by a wide audience including non-technical individuals]

Atrial fibrillation is the most common sustained arrhythmia. It is associated with a high incidence of symptoms and with multiple medical sequelae including strokes. Often, atrial fibrillation is initiated (and possibly maintained) by electrical triggers located in the pulmonary veins, and can be cured or greatly suppressed by electrically isolating the pulmonary veins from the left atrium. A variety of catheter-based ablation strategies have been pursued to effect electrical isolation of the pulmonary veins (PVs), but none provides a simple convenient means for creating a ring of ablative lesions in the left atrium around the PV ostia. The present invention is designed to accomplish this ablation strategy.

2. **Problem Solved** [Describe the problem solved by this invention]

Current ablation strategies for atrial fibrillation do not provide a convenient simple means for placing a large ring of lesions around the pulmonary vein ostia. This invention solves the problem so that ablative lesions can be placed in a consistent fashion in the left atrium around the pulmonary vein ostia. (See attached.)

3. **Novelty** [Identify those elements of the invention that are new when compared to the current state of the art]

The disclosed ablation catheter has a lumen that exits the catheter just proximal to the deflectable part of the catheter. This allows a guidewire to be advanced through the lumen and anchored in a pulmonary vein. Once the catheter is deflected, the ablative tip electrode is positioned against the left atrial endocardium outside the PV ostium. Ablative lesions can then be placed as the catheter is rotated about the axis defined by the anchoring guidewire.

SECTION B. JHU INVENTOR CERTIFICATION and ASSIGNMENT

This section is to be completed only by those JHU personnel subject to The Johns Hopkins University Intellectual Property Policy. Non-JHU Inventors, and HHMI or KKI Inventors at JHU are subject to a separate assignment and must complete Section C. JHU Inventors who believe they are not subject to The Johns Hopkins University Intellectual Property Policy for the invention described herein must complete Section C.

I/we, the Inventors, hereby certify that the information set forth in this Report of Invention is true and complete to the best of my/our knowledge.

I/we, the Inventors, hereby certify that I/we will promptly advise LTD of any commercial interest regarding the invention described herein.

I/we, the Inventor(s), subject to The Johns Hopkins University Intellectual Property Policy and not under an obligation to assign intellectual property rights to another party, hereby affirm that in consideration for The Johns Hopkins University's evaluation of commercial potential and a share of income which I/we may receive upon commercialization of my/our invention, on the date of my/our signature(s) as indicated below do hereby assign and transfer my/our entire right, title and interest in and to the invention described herein unto The Johns Hopkins University, its successors, legal representatives and assigns.

JHU Inventor Signature	Ronald Berger Typed or Printed Name	7/10/03 Date
JHU Inventor Signature	Typed or Printed Name	Date
JHU Inventor Signature	Typed or Printed Name	Date
JHU Inventor Signature	Typed or Printed Name	Date
JHU Inventor Signature	Typed or Printed Name	Date

July 3, 2003

Invention Disclosure

Catheter and Method for Ablation of Atrial Tissue

Inventor: Ronald D. Berger, MD, PhD
Associate Professor of Medicine
Johns Hopkins University

Background:

Atrial fibrillation is the most common sustained arrhythmia. It is associated with a high incidence of symptoms and with multiple medical sequelae including strokes. Recently, clinical investigators have found that in many cases, atrial fibrillation is initiated (and possibly maintained) by electrical triggers located in the pulmonary veins [1], and can be cured or greatly suppressed by electrically isolating the pulmonary veins from the left atrium [2].

A variety of catheter-based ablation strategies have been pursued to effect electrical isolation of the pulmonary veins (PVs). Initially, electrophysiologists used standard radiofrequency (RF) ablation catheters to place a sector or ring of lesions inside the proximal segment of these veins. This technique was found to be problematic because (1) success was limited due to the frequent incidence of arrhythmic triggers located at the PV ostia (proximal to the ablative lesions), and (2) the procedure carried an unacceptably high complication rate due to the subsequent development of pulmonary vein stenosis. Several catheters have been developed to apply circumferential lesions just inside the PVs using RF energy, ultrasound, or thermal energy [3-7]. These devices employ inflatable balloons or similar strategies to engage the PV and deliver energy in a radially symmetrical pattern. While these systems expedite PV isolation, they are complex to manufacture and do not solve the fundamental difficulties associated with ablating inside the PVs, listed above. A recently introduced ultrasound ablation balloon system is designed to apply a ring of lesions at the PV ostium instead of inside the vein [8], but this system is complex and will still place lesions distal to arrhythmic triggers located peri-ostially.

Electrophysiologists have recently migrated to ablation strategies in which ablative lesions are placed at the PV ostia, or even in the left atrium proper [9]. Again, the goal is to electrically isolate the PVs, but to do so with a wider ring of lesions and without placing lesions inside the PVs themselves. However, it is technically more challenging to place a set of contiguous lesions in a large ring outside the PV than to create a ring of lesions inside the vein. The ablation catheter tends to fall away from the wall of the left atrium as it is moved from point to point, making contiguity of the lesions difficult to achieve. Procedure times are often long and fluoroscopic radiation exposure can be substantial. Electroanatomical mapping techniques have been used to mitigate these problems, but manipulation of the

catheter to the many sites required for creation of large isolating rings of ablative lesions remains challenging, particularly due to the irregular three-dimensional shape and trabeculated endocardial surface of the left atrium.

Description of Invention:

The current invention is a novel catheter design that allows a wide ring of contiguous ablative lesions to be placed quickly and easily on the left atrial endocardial surface surrounding each PV. The catheter resembles a standard RF ablation catheter in that it contains a distal ablation electrode, at least one additional electrode placed proximal to the ablative electrode to allow for recording bipolar electrograms, and a deflection mechanism so that the distal portion of the catheter can be curved after it has entered the left atrial cavity.

The new catheter differs from existing deflectable ablation catheters, however, in that it has a lumen for passage of a guidewire, and the distal end of the lumen exits the side of the catheter just proximal to the deflectable portion (Figure 1). The relation of the lumen exit hole to the deflection mechanism is such that the distal portion of the catheter deflects away from the side where the lumen exit resides.

In another embodiment, the catheter has a rail along one side to allow a guidewire to be advanced along the outside of the catheter. Again, the rail ends just proximal to the deflectable portion of the catheter, and the distal portion deflects away from the side with the rail (Figure 2).

Use of the catheter is shown in Figure 3. A sheath is placed across the inter-atrial septum using standard technique. The ablation catheter is advanced through the sheath into the left atrium, and preferably manipulated into one of the pulmonary veins. A guidewire (preferably with a stiff body and soft distal segment) is advanced through the catheter so that it exits the side hole, and is further advanced deep into the vein. With the guidewire maintained in place, the catheter is withdrawn from the vein until it is back in the left atrial cavity. It is then deflected into the curved position, and advanced along the guidewire until the side of the deflected portion (including the ablation electrode) is in contact with the endocardial surface of the atrium, outside the PV ostium. Ablative energy is applied at this site, and the catheter is then rotated slightly about the axis of the guidewire to a new site. Ablative energy is applied, and the catheter is rotated again. This process is repeated until a full ring of lesions has been made. Alternatively, ablative energy can be continuously applied as the catheter is slowly and continuously rotated about the axis defined by the guidewire. In either case, the guidewire serves as an anchor to hold the catheter in radially symmetric positions relative to the vein ostium. The procedure may then be repeated for each PV.

This system provides advantages over current RF ablation catheters in that this catheter easily maintains endocardial contact over a nearly constant radius of distance outside the PV ostium. The exact curvature can be adjusted so that the catheter accommodates to the irregularities in the atrial endocardial surface. At all sites, the side of the ablation electrode is held in contact with the endocardial surface, producing larger and more consistent lesions than when the tip of the distal electrode contacts the tissue (as is often the case with current ablation catheters). Furthermore, a family of catheters can be manufactured with different radii of curvature to enable the operator to choose the appropriate radius of the ring of lesions, depending on the dimensions of the atrium in the individual patient. The catheter design is much simpler than that of inflatable balloon systems, so cost and device failures will be minimized.

The placement of a lumen in an ablation catheter for passage of an anchoring guidewire has been described [3,4,10]. However, in these previously described devices, a second, more distal achoring guidewire is required and the catheter is secured simultaneously in two pulmonary veins, so that a line of ablative lesions can be placed from one PV ostium to another, rather than in a ring around a PV ostium. These previously described catheters lack a deflection mechanism to allow the distal portion of the catheter to be adjustably curved and rotated from site to site, as in the presently described invention.

The new catheter may include other design elements found in ablation catheters, such as a thermistor or thermocouple for temperature monitoring, and a position sensor to allow for electroanatomical tracking. An additional lumen may be added for fluid delivery to enable cooling during RF delivery. Furthermore, the ablative tip could be an ultrasonic or thermal device instead of an electrode if an ablative modality other than RF energy is preferred.

References:

1. Haissaguerre M, Jais P, Shah DC, Takahashi A, Hocini M, Quiniou G, Garrigue S, Le Mouroux A, Le Metayer P, Clementy J. Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins. N Engl J Med. 1998; 339(10):659-66

2. Haissaguerre M, Jais P, Shah DC, Garrigue S, Takahashi A, Lavergne T, Hocini M, Peng JT, Roudaut R, Clementy J. Electrophysiological end point for catheter ablation of atrial fibrillation initiated from multiple pulmonary venous foci. Circulation 2000;101(12):1409-17

3. Lesh M. U.S. Patent 6,012,457 (and continuations)

4. Lesh M, et al. U.S. Patent 6,024,740 (and continuations)

5. Swartz J, et al. U.S. Patent 5,938,660 (and continuations)

6. Satake S. U.S. Patent 6,491,710

7. Stewart M, et al. U.S. Patent 6,325,797 (and continuations)

8. Meininger GR. Calkins H. Lickfett L. Lopath P. Fjield T. Pacheco R. Harhen P. Rodriguez ER. Berger R. Halperin H. Solomon SB. Initial experience with a novel focused ultrasound ablation system for ring ablation outside the pulmonary vein. J. Interventional Cardiac Electrophysiol. 8:141-148, 2003

9. Pappone C, Rosanio S, Oreto G, Tocchi M, Gugliotta F, Vicedomini G, Salvati A, Dicandia C, Mazzone P, Santinelli V, Gulletta S, Chierchia S. Circumferential radiofrequency ablation of pulmonary vein ostia: A new anatomic approach for curing atrial fibrillation. Circulation. 2000;102(21):2619-28

10. Lesh M. U.S. Patent 5,971,983 (and continuations)

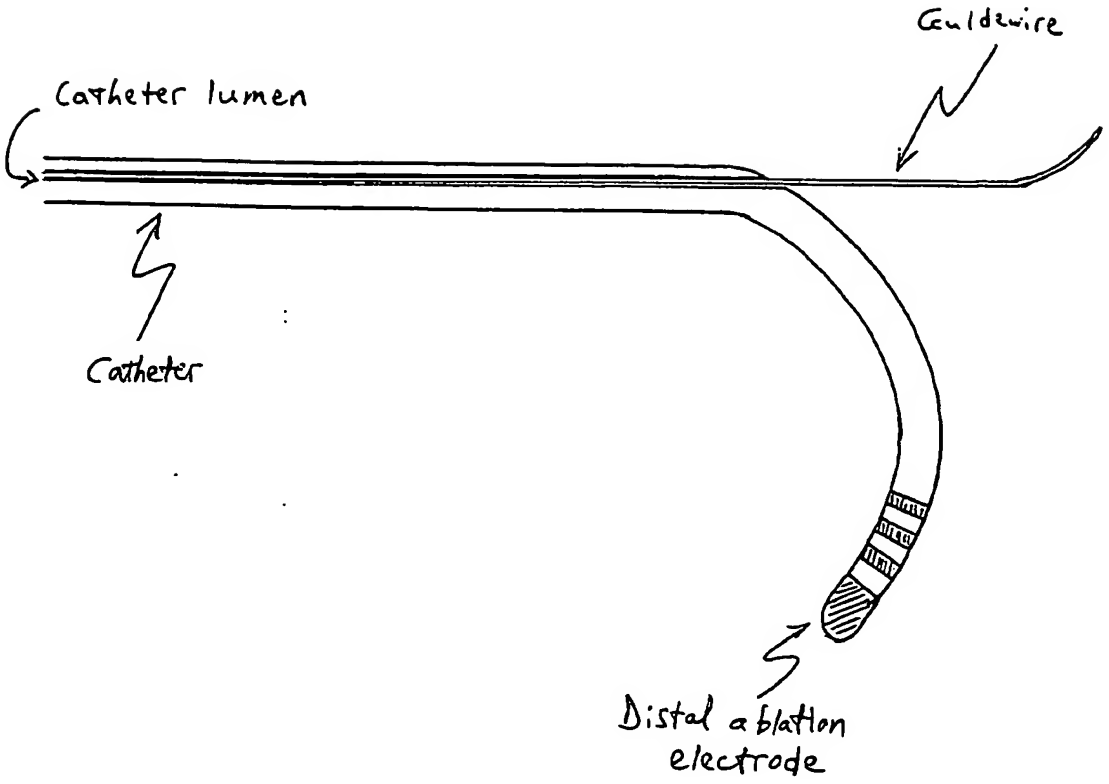
Guidewire
Catheter lumen
Catheter
Distal ablation electrode

Figure 1

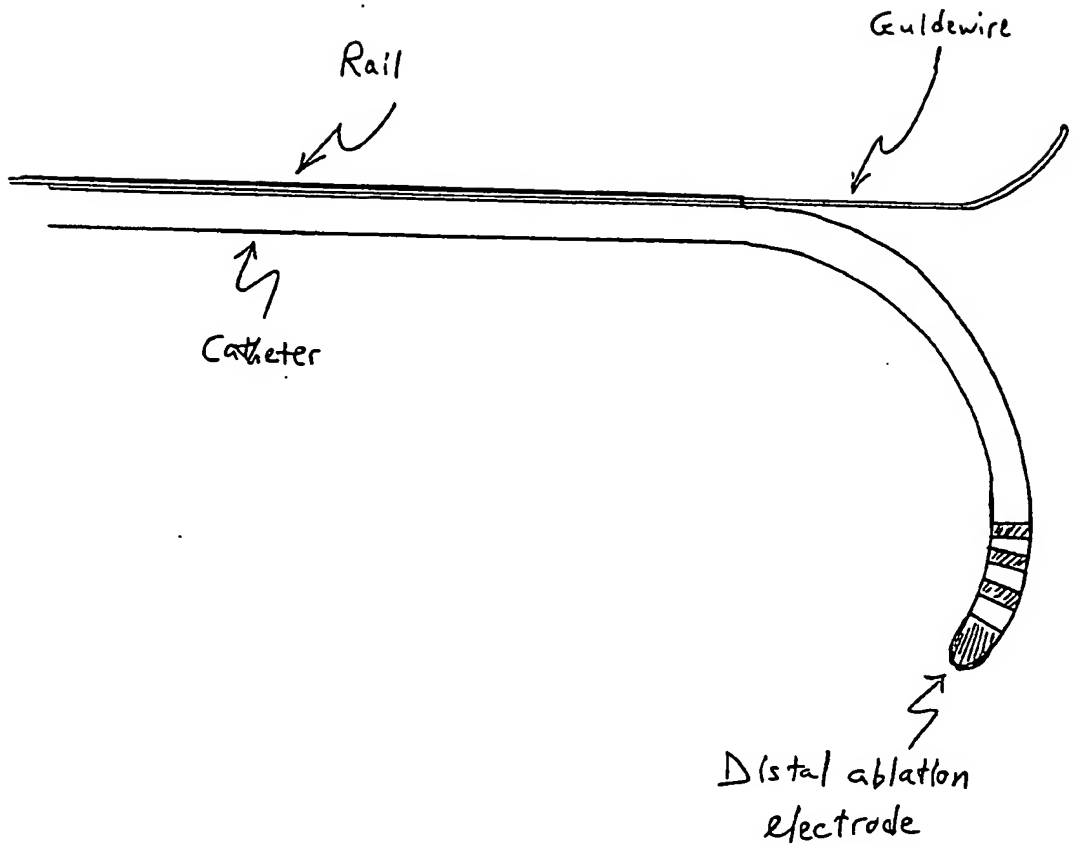

Figure 2

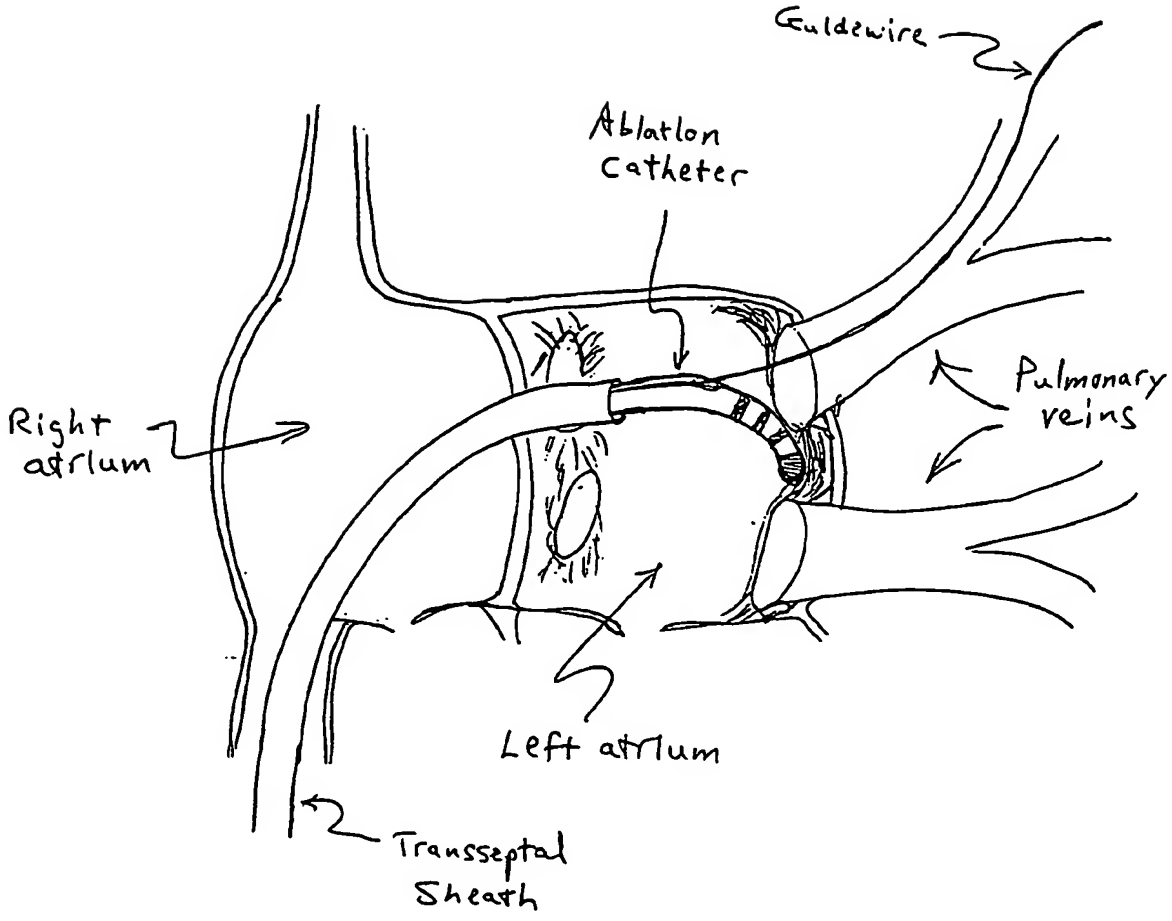
Guidewire
Ablation
Catheter
Pulmonary
veins
Right
atrium
Left atrium
Transseptal
Sheath

Figure 3

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/034864

International filing date: 20 October 2004 (20.10.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/512,657
Filing date: 20 October 2003 (20.10.2003)

Date of receipt at the International Bureau: 15 December 2004 (15.12.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse